

Attorney Docket No.: RU-0224
Inventors: Fennell et al.
Serial No.: 10/828,781
Filing Date: April 21, 2004
Page 4

REMARKS

Claims 1-8 are pending in this application. Claim 8 has been withdrawn from consideration. Claims 1-7 have been rejected. Claim 5 has been amended. Claim 8 has been canceled. No new matter has been added. Applicants are respectfully requesting reconsideration in view of the following remarks.

I. Election/Restriction Requirement

The restriction requirement placing the instant claims into Groups I-II has been deemed proper and made final. Claim 8 has been withdrawn from further consideration. Accordingly, Applicants are canceling claim 8 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Rejection of the Claims Under 35 U.S.C. §112

Claims 5-7 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite; however, the Examiner's rejection appears to be incomplete as it merely states "Claim 5 is vague and indefinite in that the." Applicants respectfully request that the missing text at the bottom of page 2 of the Office Action be provided so that Applicants can properly respond to this rejection.

Claims 1-7 have been rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make an/or use the invention. Specifically, the Examiner suggests that the invention employs a strain of

Attorney Docket No.: **RU-0224**
Inventors: **Fennell et al.**
Serial No.: **10/828,781**
Filing Date: **April 21, 2004**
Page 5

Dehalococcoides ethenogenes, wherein it is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. It is further suggested that it is unclear if the starting material were readily available to the public at the time of the invention.

Applicants respectfully traverse this rejection. It is evident that the literature predating the filing of the present application makes it clear that *Dehalococcoides ethenogenes* strain 195 was known and available. This is shown in the very art relied upon by the Examiner in the section 102 and 103 rejections. For example, the Examiner is referred to the abstract of Maymo-Gatell et al., which describes the isolation and characterization of strain 195. Moreover, Applicants provide herewith additional evidence showing that strain 195 was available to the public and was readily recognizable to one skilled in the art. For example, Seshadri et al. ((2005) *Science* 307:105-108), submitted for publication July 1, 2004, disclose the genome sequence of *Dehalococcoides ethenogenes* 195 (see abstract), thereby demonstrating that this strain was available to the public. In addition, WO 2000/063443 teaches sequences corresponding to the unique regions of the *D. ethenogenes* 195 16S rRNA that enable the identification of this bacterial strain. See page 1, lines 5-9. In particular, the Examiner is referred to page 5 (lines 19-21 and 30-31), the 16S rDNA profiles shown in Figures 1 and 2, and the passage beginning at page 23 (line 12) and ending at page 25, which describes sequences unique to the 195 strain. This preponderance of evidence demonstrates that *D. ethenogenes* 195 was known, available, and identifiable to one skilled in the art at the time the invention was made.

Attorney Docket No.: RU-0224
Inventors: Fennell et al.
Serial No.: 10/828,781
Filing Date: April 21, 2004
Page 6

Accordingly, the written description requirement has been met and it is respectfully requested that this rejection be reconsidered and withdrawn.

III. Rejection of the Claims Under 35 U.S.C. §102

Claims 5-7 have been rejected under 35 U.S.C. 102(b) as being anticipated by Maymo-Gatell et al. ((1997) *Science* 276:1568-1571). It is suggested that this reference teaches a process of bioremediation of a contaminated material using a dehalogenating microorganism, such as *D. ethenogenes* 195 with an effective amount of a simple halogenated compound and an electron donor (Figure 2).

Claims 5 and 7 have been further rejected under 35 U.S.C. 102(b) as being anticipated by DiStefano et al. ((1991) *Appl. Environ. Microbiol.* 75:2287-2292). It is suggested that this reference discloses a process of bioremediation of a contaminated material using a dehalogenating organism with an effective amount of a simple halogenated compound (Figure 1 with methanol and acetate as electron donors and Table 2).

Applicants respectfully disagree with these rejections.

Figure 2 of Maymo-Gatell et al. discloses the growth of strain 195 on H₂-PCE as well as PCE utilization and product formation. The 195 cells were grown in growth medium supplemented with ABSS (2 mM acetate, 0.05 mg of vitamin B₁₂ per liter, and 25% (v/v) anaerobic digester sludge supernatant) and 5% (v/v) extract from a mixed culture. See Figure 2 legend in view of paragraph 2, column 1, at page 1569.

Similarly, Figure 1 and Table 1 of DiStefano et al. show PCE utilization and VC and ETH product formation by a methanol-PCE

Attorney Docket No.: **RU-0224**
Inventors: **Fennell et al.**
Serial No.: **10/828,781**
Filing Date: **April 21, 2004**
Page 7

methanogenic culture. See Figure 1, Table 1, and the first full paragraph of column 1 at page 2288.

However, Applicants find no teaching in either of the cited documents of the use of a simple halogenated compound to enhance the bioremediation process of a material contaminated with a halogenated aromatic compound. In contrast, Applicants have appreciated that because a simple halogenated compound is more readily degraded, it can be used to stimulate or support the growth of dehalogenating organisms in a material contaminated with a halogenated aromatic compound. See the passage spanning page 14 (line 7) to page 16 (line 17), and page 20 (lines 6-30). Accordingly, to highlight this distinct feature of the present invention, Applicants have amended claim 5 to specify that the material being bioremediated is contaminated with a halogenated aromatic compound. Support for this amendment is found throughout the specification and specifically at page 14 (lines 7-10).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP 2131.

In so far as neither Maymo-Gatell et al. nor DiStefano et al. teach or suggest introducing into a material contaminated with a halogenated aromatic compound an effective amount of a simple halogenated compound to enhance the bioremediation process of the contaminant, these references cannot be held to anticipate the present invention. It is therefore respectfully requested that these rejections be reconsidered and withdrawn.

Attorney Docket No.: RU-0224
Inventors: Fennell et al.
Serial No.: 10/828,781
Filing Date: April 21, 2004
Page 8

IV. Rejection of the Claims Under 35 U.S.C. §103

Claims 1-7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Adrian et al. taken with Maymo-Gatell et al. in light of Bunge et al. It is suggested that Adrian et al. teach a process of dehalogenation of aromatic chlorinated compounds with a strain of *Dehalococcoides*. The Examiner suggests that Adrian et al. use a mixed culture and provide an electron donor such as hydrogen. It is acknowledged that this reference does not teach strain 195, however, it is suggested that the strain cultured is very closely related to strain 195 (Figure 2 of Adrian et al.). Bunge et al. are suggested to demonstrate that the strain taught therein has 16S ribosomal DNA having 98.5% identity with strain 195. Maymo-Gatell et al. are suggested to indicate that strain 195 is capable of dehalogenation of aliphatic compounds such as tetrachloroethene, using hydrogen, butyrate, or methanol as electron donors (page 1569, paragraph 2). The Examiner asserts that one of ordinary skill in the art would have been motivated to add a simple halogenated compound to the bioconversion medium of strain 195, given that this strain, was known to grow well on tetrachloroethene and hydrogen at the time the claimed invention was made. The Examiner concludes that it would have been obvious to modify the process of Adrian et al. by replacing strain *Dehalococcoides* CBDB1 with strain 195 in view of their close relatedness and the teachings of Maymo-Gatell et al. regarding the dehalogenating properties of strain 195 for the expected benefit of providing an effective process of bioremediation for very toxic and health-damaging environmental pollutants such as dioxins.

Applicants respectfully traverse this rejection.

Attorney Docket No.: RU-0224
Inventors: Fennell et al.
Serial No.: 10/828,781
Filing Date: April 21, 2004
Page 9

As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (A) Determining the scope and content of the prior art; (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

The combined teachings of the cited documents generally teach the dehalogenation of chlorinated compounds such as PCE and chlorobenzenes to nontoxic or less toxic compounds using strains of *Dehalococcoides*. However, there is nothing in the combined teachings of the cited documents to suggest introducing into a material contaminated with a halogenated aromatic compound an effective amount of a simple halogenated compound to enhance the bioremediation process of the contaminant.

While the Examiner suggests that one of ordinary skill in the art would have been motivated to add a simple halogenated compound to the bioconversion medium of strain 195, given that this strain was known to grow well on tetrachloroethene and hydrogen at the time the claimed invention was made, tetrachloroethene is a known groundwater pollutant that is highly toxic and is suspected to be a human carcinogen. See page 1568 of Maymo-Gatell et al. Thus, common sense would NOT lead one skilled in the art to introduce this compound into a material that is already contaminated with a halogenated aromatic compound.

Attorney Docket No.: RU-0224
Inventors: Fennell et al.
Serial No.: 10/828,781
Filing Date: April 21, 2004
Page 10

Furthermore, there would be no rationale for one skilled in the art to modify the process of Adrian et al. by adding a simple halogenated compound to support growth because Adrian et al. indicate that "[t]he presence of chlorobenzene as an electron acceptor and hydrogen as an electron donor is essential to growth, and indicates that strain CBDB1 meets its energy needs by a dehalorespiratory process." See abstract. Thus, the halogenated aromatic compound itself is sufficient to support growth and introduction of a simple halogenated compound would not be necessary or obvious based upon the teachings of Adrian et al.

There is simply an insufficient rationale to combine the teachings of the cited references to arrive at the invention as presently claimed. Accordingly, it is respectfully requested that that this rejection under 35 U.S.C. 103(a) be reconsidered and withdrawn.

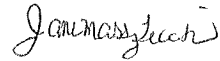
V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

Attorney Docket No.: RU-0224
Inventors: Fennell et al.
Serial No.: 10/828,781
Filing Date: April 21, 2004
Page 11

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Jane Massey Licata
Registration No. 32,257

Date: July 24, 2008

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515